REMARKS

The present application is directed to methods, devices, and kits for the detection, concentration or isolation of an analyte in a sample. In particular, the application relates to the concentration of an analyte using an assay such as an immunoassay.

Claims 1, 5, 6, 9-16 and 20-25 are currently amended. New Claims 26-30 are added. Claims 8 and 17-19 are cancelled without prejudice. Claims 1-7, 9-16 and 20-30 are pending. Favorable consideration of the currently pending claims is respectfully requested in light of the following amendments and remarks. No new matter is added and support for the amendments may be found throughout the specification and original claims.

Claim rejections under 35 U.S.C. § 102(b)

In the Office Action mailed December 1, 2005, the Examiner rejected Claims 9, 10 and 20 under 35 U.S.C. § 102(b) as being anticipated by Noda *et al* (U.S. Patent No. 5,900,379). Applicant respectfully traverses.

Noda *et al.* disclose an analytical device comprising, in part, a cassette (see claims 1-2). The cassette is defined, as a strip containing a first absorbent material (element 1 of drawings), **a membrane immunoassay** (element 2 of drawings), and a second absorbent material (element 3 of drawings), "**attached to**" a cassette support means (element 4 of drawings), (see column 5, lines 58-61; and column 7, line 66 through column 8, line 1). Noda *et al.* teach that the first absorbent material, the second absorbent material, or both may be removed from the cassette (see column 4, lines 9-11). The entire cassette, then, can either be discarded, or the first absorbent material and the second absorbent material can be removed from the cassette, **leaving the results section attached to the cassette** (the membrane immunoassay) to be stored (see column 5, lines 35-44; and column 11, example 1). Applicant also respectfully directs the Examiner to Figures IA and IB wherein the membrane immunoassay (element 2) is clearly depicted as a distinct zone of the cassette. Furthermore, the first and second absorbent materials (elements 1 and 3, respectively) based on the

teachings of Noda *et al.* are discarded as discussed above, leaving the membrane immunoassay attached (see Figure 10A). **Noda *et al.* fail to disclose or suggest that the membrane immunoassay (detection zone) is entirely separable from the remainder of the cassette or cassette support means.**

Claim 1 has been amended to clarify that the detection zone containing the bound analyte and immobilized binding partner is separated or separable from the remainder of the device and that the **separated detection zone** is analyzed. Support for this limitation can be found on at least page 15, lines 11-16 and the working examples. In particular, Example 2, starting on page 23 of the instant application, discloses removal of the detection zone (membrane) from the remainder of the device. Claim 9 depends from amended claim 1. Applicant respectfully asserts Noda *et al.* fail to teach or suggest removal of the detection zone containing the bound analyte and immobilized binding partner (the membrane immunoassay) from all other zones and the remainder of the device as now claimed herein.

Furthermore, Applicant respectfully submits that Claim 1 has been amended to recite a method for **detecting, isolating or purifying an organism** and wherein the **analyte is an organism**. In contrast, Noda *et al.* is directed to the collection and storage of biological fluids such as urine (see abstract). Applicants respectfully submits that Noda *et al.* teach the disposal of microorganisms from biological fluids "For example, growth in the absorbent material of microorganisms present in the urine can be prevented because the absorbent material can be easily removed from the cassette. Thus, the result of the analysis can be stored without that portion of the analytical device containing most of the urine" (see column 5, lines 39-44). Therefore, Applicant respectfully submits that Noda *et al.* fail to teach or suggest the claimed method.

Additionally, amended Claim 10 recites a device, wherein the analyte is an organism and that the detection zone of the device is separated from the remainder of the device. Applicants respectfully submit Noda *et al.* fail to teach or suggest the claimed device. Support for this limitation can be found on page 19, lines 17-20 of the instant application.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §102(b).

Claim rejections under 35 U.S.C. § 102(e)

In the Office Action of December 1, 2005, the Examiner rejected Claims 1-4, 7, 9, 10 and 20 under 35 U.S.C. § 102(e) as being anticipated by LaBorde (U.S. Patent No. 6,607,922). Applicant respectfully submits that the amendments to the claims overcome the Examiner's rejection.

LaBorde teaches an immunochromatographic assay method that relates broadly to lateral flow devices employing superparamagnetic particles as labels for the analyte to be detected. The bound complexes are captured in a predetermined area of the porous analytical membrane termed the "capture region" or "capture zone" (see column 3, line 1; and element 14 of the drawings). The lateral flow device as defined by LaBorde contains: an assay support member (element 11 of drawings); a sample receiving element (element 17 of drawings); an immunoassay test strip containing a porous analytical membrane (element 13 of the drawings); at least one **capture region** (element 14 of the drawings); a backing member (element 12 of drawings); and a protective member (element 15 of drawings) with at least one magnetic standard line printed on the protective membrane (element 16 of the drawings).

Claims 1, 9 and 10 have been amended to clarify that the detection zone is separated from the other zones as well as the remainder of the device. Support for this amendment can be found on, at least, page 3, lines 17-18, lines 24-27, and line 35 through page 4, line 2; page 4, lines 15-20; page 5, lines 19-20; and page 15, lines 11-16. LaBorde fails to teach or suggest separating the capture region (element 14 of drawings) containing the bound analyte and the immobilized binding partner from all other zones and the remainder of the device. Indeed, LaBorde teaches the removal and analysis of the **entire test strip and not the detection zone** (See Figures 5 and 7 and column 5, lines 47-59).

Additionally, Applicant submits that amended Claim 1 is directed to a method for detecting, isolating or purifying an organism. LaBorde fails to teach or suggest detecting, isolating or purifying an organism and cannot therefore anticipate each and every element as claimed herein.

Regarding Claim 9, the Examiner concluded LaBorde fails to teach a kit other than the device itself. Applicant respectfully submits that amended Claim 9 is not taught by LaBorde for at least the reasons discussed above.

Applicant respectfully asserts that the amended claims are not taught or suggested by LaBorde. Accordingly, Applicant respectfully request withdrawal of the rejection under 35 U.S.C. §102(e).

Claim rejections under 35 U.S.C. § 103(a)

In the Office Action of December 1, 2005, the Examiner rejected Claims 5-6 under 35 U.S.C. §103(a) as being unpatentable over LaBorde (already of record) in view of Benjamin *et al* (U.S. Patent No. 5,491,068, hereinafter Benjamin). Applicant respectfully submits that the amendments to the claims overcome the rejection.

As discussed above under section 35 U.S.C. §102(e) LaBorde fails to teach that any or all of the **detection zone** comprising the bound analyte and immobilized binding partner is removed from the device.

LaBorde teaches a test strip comprising a porous membrane (element 13) that includes the capture zone (element 14), a backing member (element 12) and a **protective member** (opaque surface or cover)(element 15 of drawings). LaBorde deems the protective member critical because **without the protective surface the porous nitrocellulose membrane would be damaged** by rubbing across detection coil 34, thereby producing incorrect or unreliable readings, or both (see column 6, lines 6-12). Applicant submits the use of an opaque cover (protective member) over the detection zone as taught by LaBorde would hinder one's ability to remove at least part of the detection zone as claimed herein.

Applicant submits the deficiencies of LaBorde are not satisfied by Benjamin for at least the following reasons. Benjamin fails to teach a device comprising a plurality of zones. Benjamin discloses magnetic beads having immobilized antibodies. Neither LaBorde or Benjamin teach or suggest removal of a detection zone from a test strip. Therefore, the amended claims would not have been obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 103(a).

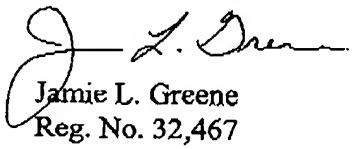
CONCLUSION

Based upon the amendments and remarks provided above, Applicant believes that the pending claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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